

## REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the Office Action dated September 21, 2004 (hereinafter, "Office Action").

Claims 1-19 and 21-23 are pending in the present application upon entry of the present Amendment. Claims 1, 17 and 18 have been amended to incorporate recitations of Claim 20. Accordingly, Claim 20 has been canceled, and Applicants submit that the claim amendments do not present new matter and respectfully request entry thereof.

The issues presented in the Office Action are addressed below.

### **I. Claim Rejections Under 35 U.S.C. § 103**

Claims 1-19 and 21-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/05846 to Nebe (Nebe), U.S. Patent No. 5,696,236 to Omar et al. (Omar et al.) and EP 0798003A2 to Savage et al. (Savage et al.) for reasons of record. In particular, on page 5, the Office Action states the following:

It would have been obvious to one of ordinary skill in the art to utilize a depth filter, which is ordinarily used in the art as a prefilter for ultramembrane filtration (Savage et al., page 2, lines 47-48), for removal of prion particles from a liquid based on the teaching of Nebe which indicated that half of the infectious prion was removed using the nylon premembrane filter (depth filter) indicating that the prion has a high nonspecific affinity for the prefiltration media. Furthermore, one having ordinary skill in the art would have high expectation of success utilizing the matrices of Omar et al. and Savage et al. for removal of infectious agent from blood plasma products.

Applicants respectfully disagree with this assertion.

Claim 20 is not subject to the rejection under 35 U.S.C. § 103. In an effort to expedite prosecution, Applicants have incorporated the recitations of Claim 20 (underlined) into Claim 1. Amended Claim 1 now recites:

A method of removal of abnormal infective prion proteins associated with transmissible spongiform encephalopathies (TSEs) from an aqueous liquid containing a natural product, which comprises passing the liquid through a depth filter formed of a matrix comprising solid particles of porous material and having a pore size providing a retention less than 6  $\mu\text{m}$ , and so removing ~~any~~ abnormal infective

prion proteins which may be present in the liquid **such that the liquid is non-infective with respect to prion protein infectivity.**

Claims 17 and 18 have been amended to include similar recitations.

Accordingly, Applicants respectfully submit that Claims 1-19 and 21-23 are not obvious in view of the cited references, and request that the rejection of Claims 1-19 and 21-23 be withdrawn.

## **II. Claim Rejections Under 35 U.S.C. § 102**

Claims 1-19 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,407,212 to Morgenthaler et al. (Morgenthaler). More specifically, the Office Action states that "Morgenthaler et al. disclose a method of removing prion from a blood sample using filter binding agents which are selected from kieselguhr, perlite or diatomaceous earth and contacting the blood product with the filter binding agent before filtration of the liquid through a membrane filter. In this instance the filter binding agent forms the use of a prefilter by preventing the membrane filter from clogging. Therefore, the instant invention is anticipated by Morgenthaler et al." Office Action, pages 6-7. Applicants respectfully disagree with this assertion.

Claim 20 is not subject to the rejection under 35 U.S.C. § 102(e). As noted above, Applicants have incorporated the recitations of Claim 20 into Claim 1. Claims 17 and 18 have been amended to include similar recitations.

Accordingly, Applicants respectfully submit that Claims 1-19 and 21-23 are not anticipated in view of Morgenthaler, and request that the rejection of Claims 1-19 be withdrawn.

## **III. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

### **A. Enablement Rejection**

Claims 1-23 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. In particular, the Office Action states that "while being enabling for removing some prion molecules from a sample, does not reasonably provide enablement for every single (all) prion molecules from the same sample." Office Action, page 7.

Applicants respectfully submit that Claim 1 has been amended to delete the recitation directed to removal of "any" abnormal infective prion proteins and now recites that the "liquid is non-infective with respect to prion protein infectivity". Claims 17 and 18 have been similarly amended. Moreover, the enclosed article, Reichl et al. Studies on the removal of a bovine spongiform encephalopathy-derived agent by processes used in the manufacture of human immunoglobulin. *Vox Sanguinis* 83:137-146 (2002), further demonstrates that the liquid is non-infective after treatment as recited in the present claims.

Accordingly, Applicants respectfully submit that Claims 1-19 and 21-23 are enabled, and request that the rejection under U.S.C. §112, first paragraph, as lacking enablement, be withdrawn.

#### **B. Written Description**

Claims 1-23 stand rejected under 35 U.S.C. §112, first paragraph, as lacking written description. The Office Action states that "the instant specification does not provide a written description for 'removing any', 'completely removing' or 'any prion contained in the protein containing solution is removed' and providing a method of determining that the level of removal is achieved." Office Action, page 8. Applicants respectfully disagree with this assertion.

As noted above (Section III. A.), Claim 1 has been amended to delete the recitation "any." Claims 17 and 18 have been similarly amended.

Accordingly, Applicants respectfully submit that Claims 1-19 and 21-23 comply with the written description requirement, and request that the rejection under U.S.C. §112, first paragraph, as lacking written description, be withdrawn.

#### **IV. Claim Objections**

Claims 21 and 22 stand objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. *See* Office Action, page 9.

Applicants respectfully submit that this objection has been overcome in view of the amendment of Claim 1 to delete the recitation "any" as noted above. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**Conclusion**

Applicants respectfully submit that, for the reasons discussed above, the references cited in the present rejection do not disclose or suggest the present invention as claimed. Accordingly, Applicants respectfully request allowance of all the pending claims and passing this application to issue. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

It is not believed that any fee(s), including fees for additional claims, are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Applicants authorize that any additional fees believed to be due in connection with this paper may be charged to Deposit Account No. 50-0220.

Respectfully submitted,



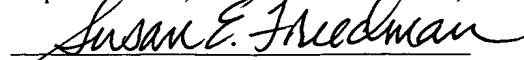
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Susan E. Freedman  
Date of Signature: February 22, 2005